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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,754	04/18/2005	Peter G. Klimko	2439 US F	6065

7590 05/13/2008

Alcon Research
6201 South Freeway
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EXAMINER	
MABRY, JOHN	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,754	KLIMKO ET AL.	
	Examiner	Art Unit	
	John Mabry, PhD	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5* is/are pending in the application.

4a) Of the above claim(s) *4 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

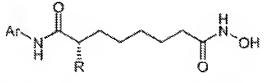
1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/07, 7/20/07, 12/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant is respectfully reminded that it is required that all claims be amended to elected group. The elected group is limited to only the species set forth. The method outside this scope has not been examined. Examiner also warns Applicant not to introduce new matter when amending.

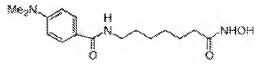
Examiner's Response

Applicant's response on February 29, 2008 filed in response to the Election/Restriction dated January 30, 2008 has been received and duly noted. The Examiner acknowledges Applicants' election of Group I with traverse. The Applicant respectfully requested Groups I, II and IV should be examined together, because the compounds in said groups are related as follows:



Ar = phenyl, 8-quinolinyl, 3-pyridyl, or 4-aminophenyl; and R = H or NH-C(O)-phenyl.

The Examiner has reconsidered the restriction requirement and has kindly examined



Groups I, II and IV. However, the species: ,

does not fall into Applicants' requested genus, but will be considered and examined in this Office Action.

Thus, the restriction requirement is deemed proper and **FINAL**.

In view of this response, the status of the rejections/objections of record is as follows:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the phrase "etc." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

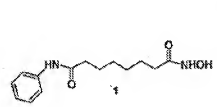
Claims 1-3 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

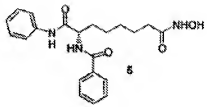
which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no evidence/written description in the specification for treatment of ocular neovascular or edematous disease or disorder using elected compounds. Additionally, there are no examples or reduction to practice of said groups.

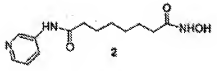
The methodology for determining adequacy of written description to convey that Applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 'Written Description" Requirement; (Federal Register/Vol 66. No. 4, Friday, January 5, 2001;11 Methodology for Determining Adequacy of Written Description (3.)).

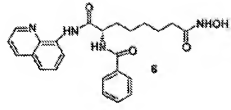
Claim Coverage

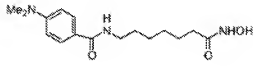
The instant application claims a method for treating persons suffering from an ocular neovascular or edematous disease or disorder using a pharmaceutically effective amount of an HDAC inhibitor. The HDAC inhibitors used in this method are:











The claimed methods (using compounds above) are used to treat a large scope of diseases and disorders as shown below (see page 5 of Specification):

> diabetic retinopathy, chronic glaucoma, retinal detachment, sickle cell retinopathy, age-related macular degeneration, rubeosis iritis, uveitis, neoplasms, Fuch's heterochromic iridocyclitis, neovascular glaucoma, corneal neovascularization, neovascularization resulting from combined vitrectomy and lensectomy, retinal ischemia, choroidal vascular insufficiency, choroidal thrombosis, carotid artery ischemia, contusive ocular injury, retinopathy of prematurity, retinal vein occlusion, proliferative vitreoretinopathy, corneal angiogenesis, retinal microvasculopathy, and retinal (macular) edema.

Applicants' Reduction to Practice

According to the Specification at the time of filing, Examiner has concluded that Applicant was not in possession of the claimed invention.

Level of Skill and Knowledge in the Art

The ordinary artisan is highly skilled, e.g. a masters or PhD in the biomedical medical sciences or a medical doctor, etc. The level of skill in the art is high because of experimentation may be expansive and unpredictable.

Any one drug cannot treat all of these diseases and disorders, disclosed in the specification on page 5, generally. These are all different diseases and disorders, which occur by different modes of action. The specification is drawn to an elaborate list of different ocular and edematous disorders and diseases, all of which cannot be treated by any one drug.

According to the MPEP §2163 I. A. "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has been described with sufficient particularity such that one skilled in the art would recognize that eh applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the area or known to one of ordinary skill in the art." The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see I) (A), above), reduction to drawings (see I)(B), above), or by disclosure of relevant, identifying characteristics coupled with a known or disclosed

correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see I)(C), above). See Eli Lilly, 119 F.3d at 1568, 43, USPQ2d at 1406."

As discussed above, the treatment of ocular neovascular or edematous disease or disorder using elected compounds is not art recognized in the Specification.

According to the MPEP §2163.02 Standard for Determining Compliance with the Written Description Requirement,

> "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". *In re Gosteli*, 872, F.2d 1008 1012, 10 USPQ2d 1614, 1618 (Fed. Cir.1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of filing date sought, he or she was in possession of the invention, an that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter". *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177,

179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 217 USPQ 1089, 1096 (Fed. Cir. 1983))."

Working Examples and Guidance Provided

The Specification does not demonstrate any support for treatment of ocular neovascular or edematous disease or disorder using elected compounds. There are no working examples of treatment of ocular neovascular or edematous disease or disorder using elected compounds *in vivo* or *in vitro*. The Specification does not even meet the minimum art recognized experimental standards such as using the elected compounds in cell culture experiments. The specification lists a large number of diseases and disorders as described above. In the prior art, the elected compounds are particularly preferably used for treatment of cancer, particularly tumors. However, there are no examples using art recognized models of these diseases disclosed in the instant applicant. There is no data is provided in the Specification that teaches how to treat ocular neovascular or edematous disease or disorder using elected compounds as a therapeutic agents.

State of the Art and Analysis of the Issues

The nature of the invention is treatment of ocular neovascular or edematous diseases or disordesr using elected compounds; the state of the prior art is not well developed and is highly unpredictable. According to the Specification, Applicant's compounds (as listed above) are alleged to exhibit inhibitory activity. However, the Specification does not set forth any the *in vitro* assays. There are no teachings of how

to use the claimed compounds *in vivo*. There is insufficient disclosure to reasonably predict that the methods and compositions of the instant Specification would treat ocular neovascular or edematous disease or disorder using elected compounds *in vitro* or *in vivo*. This is merely an unsubstantiated assertion with no evidence to support the contention that election species would inhibit HDAC in order to treat ocular neovascular or edematous diseases or disorders. Applicant has not shown any cell culture data or *in vivo* studies for treating affected patients. The Applicant has not shown any art recognized correlation between the data shown and the scope of the claimed invention.

Even in the event the Applicant did provide *in vivo* and *in vitro* studies, the ordinary artisan would recognize and appreciate that there is no known correlation between *in vitro* and *in vivo* results, because the artisan recognizes that an *in vitro* assay cannot duplicate the complex conditions of *in vivo* therapy. In the *in vitro* assay, the agent is in contact with cells during the entire exposure period. This is not the case *in vivo* where exposure to the target site may be delayed or inadequate. In addition, variables such as biological stability, half-life, or clearance from the blood are important parameters in achieving successful therapy. The composition may be inactivated *in vivo* before producing a sufficient effect, for example, by proteolytic degradation or immunological activation. In addition, the composition may not reach the target cells because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells, and tissues where the composition has no effect and/or a large enough local concentration may not be established. There are no specific teachings in the disclosure that would allow one to have a reasonable expectation of

success in transferring the *in vitro* method to treat affected patients. One is only left with speculation and an invitation to experiment. Given the breadth of the claims which encompass treatment of ocular neovascular or edematous diseases or disorders using elected compounds and the lack of examples and guidance as discussed above, one of ordinary skill in the art would reasonably have considered that at the time the application was filed, that the Applicant was not in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al (WO 00/08048).

Mori teaches the use an HDAC inhibitor for the treatment of ophthalmic conditions, such as uveitis and diabetic complications. See the abstract, page 12, lines 26-30 and claim 7. The above reference makes clear that the claimed method of use well known. Thus, said claim is anticipated by Mori et al.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

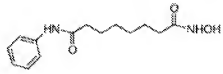
A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Besterman et al (US 6,953,783 B1). Claims 1-3 and 5 are drawn to a method for treating persons suffering from an ocular neovascular or edematous disease or disorder using an effective amount of an HDAC inhibitor (using the compounds of the elected group).

Besterman et al discloses the compound, 1-N-hydroxy-8-N-phenyl octanediamide, (as shown below) used in a method to inhibit histone deacetylase (HDAC) which demonstrates the treatment of tumor growth in a mammal (see column 16, lines 55-67 and column 17, lines 1-24 and column 36, Example 10).



The instant application claims the compound, 1-N-hydroxy-8-N-phenyl octanediamide, (as shown above) used in a method to inhibit histone deacetylase (HDAC). Thus claims 1-3 and 5 are anticipated by Besterman et al.

The reference shows the compound and the method of treating cancer, but is silent on particularly treating persons suffering from an ocular neovacular or edematous disease or disorder. The compound in said reference will inherently treat a person suffering from an ocular neovascular or edematous disease or disorder (as claimed in the instant application) because the compound, 1-N-hydroxy-8-N-phenyl octanediamide is shown to inhibit histone deacetylase (HDAC). The Applicant asserts that HDAC inhibitors inhibit VEGF induced neovascularization and therefore useful for the treatment of a human patient suffering from an ocular or edematous disease or disorder (see Specification, page 5, lines 11-26). Due to the inhibition of HDAC with said compound, as described by Besterman, the instant claimed compound, 1-N-hydroxy-8-N-phenyl octanediamide, would inherently treat a person suffering from an ocular neovascular or edematous disease or disorder.

Additionally, Besterman discloses a method in which the compound, 1-N-hydroxy-8-N-phenyl octanediamide, can be used to treat inflammation in humans (see column 16, lines 49-54). According to the claimed invention, said compound is used to treat edema. One of the results of edema is inflammation.

MPEP 2112 states:

"Something which is old does not become patentable upon the discovery of a new property

"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In this case, the "unknown property" is the particular stereochemistry. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

"A rejection under 35 U.S.C. 102/103 can be made when the prior art product seems to be identical except that the prior art is silent as to an inherent characteristic

Where applicant claims a composition of matter in terms of a function, property or characteristic and the composition of matter of the prior art is the same as that of the claim but and/or Applicant has not clearly distinguished the identity of the composition of matter in the prior art from the composition of matter instantly claimed, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection."

In another example, certain claims of *Ex parte Raychem Corp.* 25 USPQ2d 1265 required a linearity ratio of less than 1.2. The decision notes that neither reference discloses any values of the linearity ratio. The PTO presented no reasoning as to what the ratio would be expected to be in the references. The Decision states: "However, this does not end the inquiry since, where the Patent and Trademark Office is not equipped to perform the needed testing, it is reasonable to shift the burden of proof to Raychem to establish that (1) the argued difference exists...."

And indeed, there have been a number of cases in which applicants have

pointed to silence of the prior art with regard to this or that property: *In re Pearson*, 181 USPQ 641; *In re Zierden* 162 USPQ 102; *In re Lemin*, 140 USPQ 273; *Titanium Metals Corporation of America v. Banner*, 227 USPQ 773; *In re Benner*, 82 USPQ 49, *Zenith Laboratories Inc. v. Bristol-Myers Squibb Co.* 30 USPQ2d 1285, 1288. Going further, if silence about properties of prior art compounds could be relied on, then one could not reject over references with no utility (see *In re Schoenwald*, 22 USPQ2d 1671), since applicants could always insert the utility into the claim as a property.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

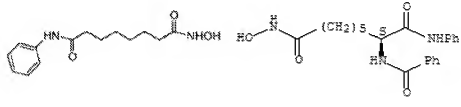
> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, or 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

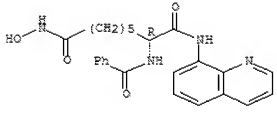
Overcoming the rejection is very straightforward. One simply replicates the prior art procedure. If the particular compound, 1-N-hydroxy-8-N-phenyl octanediamide does not appear impede tumor growth and treat ocular or edematous disease or disorder, or if on repetition, it sometimes does not treat both prior art and claimed diseases and disorder, then the rejection is overcome. Evidence should be presented in the

declaration form.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Breslow et al (US 6,511,990 B1). Claims 1-3 and 5 are drawn to a method for treating persons suffering from an ocular neovacular or edematous disease or disorder using an effective amount of an HDAC inhibitor (using the compounds of the elected group).

Breslow et al discloses the claimed compounds (as shown below) used in a method to inhibit histone deacetylase (HDAC) which demonstrates the treatment of tumor growth in a mammal (see column 11, lines 56-60 and see entire disclosure).

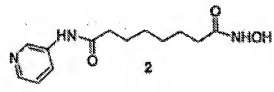




Said claims are inherently anticipated by Breslow for the reasons as stated above in rejection over Besterman et al. Thus claims 1-3 and 5 are anticipated by Breslow et al.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Butler et al (Clinical Cancer Research 2001, 7, 962-970). Claims 1-3 and 5 are drawn to a method for treating persons suffering from an ocular neovascular or edematous disease or disorder using an effective amount of an HDAC inhibitor (using the compounds of the elected group).

Butler et al discloses the claimed compounds (as shown below) used in a method to inhibit histone deacetylase (HDAC) which demonstrates the treatment of tumor growth in a mammal (see abstract and entire reference).



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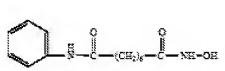
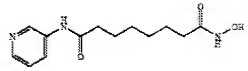
Said claims are inherently anticipated by Butler for the reasons as stated above in rejection over Besterman et al. Thus claims 1-3 and 5 are anticipated by Butler et al.

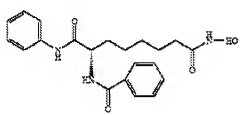
Claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Richon et al (US 2006/0079551 A1). Claims 1-3 and 5 are drawn to a method for treating persons suffering from an ocular neovascular or edematous disease or disorder using an effective amount of an HDAC inhibitor (using the compounds of the elected group).

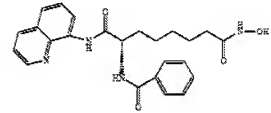
Richon et al discloses the claimed compounds (as shown below) used in a method to inhibit histone deacetylase (HDAC) which demonstrates the treatment of

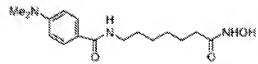
cancer in a mammal (see abstract and entire reference).











Said claims are inherently anticipated by Richon for the reasons as stated above in rejection over Besterman et al. Thus claims 1-3 and 5 are anticipated by Richon et al.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

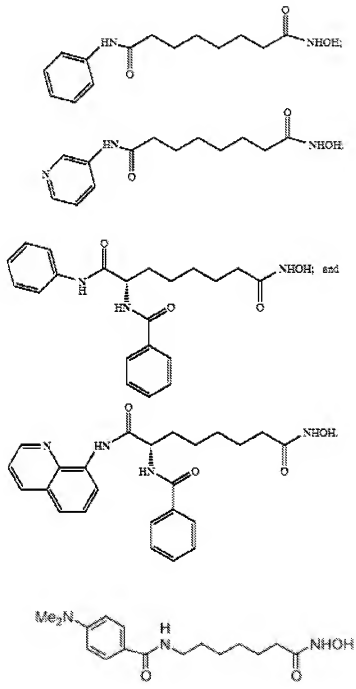
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. US 2004/0092558 A1 (10/697,135). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

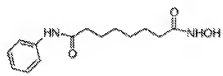
2004/0092558 discloses a method for treating persons suffering from an ocular neovascular or edematous disease or disorder using an effective amount of an HDAC inhibitor using the following compounds:



This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. US 2008/0004311 A1 (11/836,309), claims 1-4 of copending Application No. US 2004/0092431 A1 (10/694,309) and claims 1-4 of copending Application No. US 2007/0088045 A1 (10/531,747). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

The aforementioned applications disclose methods for treating persons suffering from an ocular neovascular or edematous disease or disorder using an effective amount of an HDAC inhibitor using the following compound:



Although applications US 2008/0004311 A1, 2004/0092431 A1 and 2007/0088045 A1 do not have the same inventive entity, the claims are in conflict with the instant application. It is noted that said conflicting applications have the same assignee. Who is the actual inventor of this method?

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry, PhD/
Examiner
Art Unit 1625

/Rita J. Desai/
Primary Examiner, Art Unit 1625